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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/634,038	08/08/2000	Gregory S. Keller	206066	5444

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/634,038

Applicant(s)

KELLER, GREGORY S. CM

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 16, 17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11, 16, 17 and 19 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

2. Furthermore, the references listed in the IDS filed 8-8-02 were not contained within the file wrapper of parent application 09/003,378. At the time of examination the "foreign" document (AU) and all of the "other documents" (AV-BU) were not considered. Examiner formally requests Applicant to furnish these references in response to this office action.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-8,11,16,17 are rejected under 35 U.S.C. 102(e) as being anticipated by Naughton US Pub. No. 2002/0038152 A1.

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5. Naughton discloses in abstract and paragraphs 14-17,21-22,28-29,33-34,46-56,64,67, and 74 a method of corrective surgery of a vocal cord defect comprising the steps of retrieving cells from the patient's skin, culturing the cells in vitro with collagen, and implanting the cells by injection. The cultured cells may be fibroblasts or adipocytes.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4,6-11,16,17,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boss Jr US PN 5,591,444 in view of Daniels et al. US PN 3,949,073.

Boss Jr discloses in line 22 of col. 3 through line 37 of col. 6 a method of corrective surgery comprising the steps of obtaining dermal fibroblast cells from the patient, culturing the cells in vitro, and implanting the cells by injection or engraftment. Boss Jr discloses example applications of the method such as depressed scars and wrinkles, but not expressly for vocal cord and furthermore lacks the express disclosure of including collagen or a phosphate buffered solution. Daniels et al. teaches a method of corrective surgery in lines 17 of col. 2 through line 59 of col. 5 for depressed scars and wrinkles as well as vocal cord defects. Furthermore, Daniels et al. discloses a

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rinsing step utilizing a phosphate buffered saline solution and the use of collagen to cause rapid colonization after implantation.

Therefore it would have been obvious to one of ordinary skill in the art to modify the method disclosed by Boss Jr by utilizing a phosphate buffered solution to rinse the cells, incorporate collagen in order to cause rapid colonization after implantation, and apply the method to tissue of the vocal cord to correct vocal cord defects as taught by Daniels et al.

8. Claims 9-10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton US Pub. No. 2002/0038152 A1 in view of Boss Jr US PN 5,591,444.

Naughton discloses the steps of claims 9-10 as described above but lacks the express written disclosure of using the patient's serum as a medium and engraftment as a method of implantation. Boss Jr discloses in lines 24-31 a method for corrective tissue surgery wherein the cultured cells are placed in the patients serum for transportation and may be implanted by engraftment in order to repair the damaged tissue.

Therefore it would have been obvious to one of ordinary skill in the art to modify the method disclosed by Naughton by utilizing the patient's serum as a medium in order to provide a biocompatible medium implant the cultured cells by engraftment in order to repair the damaged tissue as taught by Boss Jr.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



WHM

May 4, 2003


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700